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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,728	01/17/2002	John Victor Lamont	111723	2576

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EXAMINER

FORMAN, BETTY J *13*

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 03/27/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/046,728

Applicant(s)

LAMONT ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-16 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1634

FINAL ACTION

1. This action is in response to papers filed 9 December 2002 in Paper No. 12 in which claims 1, 3, 4 and 14 were amended and claim 2 was added. All of the amendments have been thoroughly reviewed and entered. The previous rejections in the Office Action of Paper No. 10 dated 9 August 2002 under 35 U.S.C. 112, second paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 102(e) and 35 U.S.C. 103(a) are maintained. New grounds for rejection necessitated by amendment are discussed below. All of the arguments have been thoroughly reviewed and are discussed below.

Claims 1 and 3-14 are under prosecution.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 and 3-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 3-14 are indefinite in Claim 1 for the recitation "detecting a signal representing a first molecule" because "representing" is a non-specific relational term. Therefore, the relationship between the "signal" and the "first molecule" is undefined. It is suggested that Claim 1 be amended to define the relationship e.g. replace "representing" with "from".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1 and 4-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Noblett (U.S. Patent No. 6,362,004, filed 9 November 1999).

Regarding Claim 1, Noblett discloses a method of imaging an array of discrete reaction sites on the surface of a solid support to detect the presence of molecules on the array, said molecules being detectably labeled (Column 6, lines 64-67) comprising: imaging the array and detecting a signal representing a first molecule located on the solid support at a known position (i.e. fiducial mark, Column 5, lines 32-56) by reference to the first molecule aligning inspection windows in registration with the discrete reaction sites (Column 3, lines 32-35) and determining the amount of detectable signal in each window (Column 3, lines 24-35; Column 7, lines 21-67 and Claims 13-16) wherein detection of the first molecule is carried out by aligning a first inspection window within a region of the support that includes the first molecule and searching (scanning) within the window for an image of the first molecule (Column 7, line 21-Column 8, line 4).

Regarding Claim 4, Noblett discloses the method wherein after detecting the first molecule, the first inspection window is repositioned so that one or more reaction sites is located within the window, detecting the one or more sites and by reference to the first molecule, aligning a further inspection window (Column 7, line 61-Column 8, line 4 and Claim 15).

Regarding Claim 5, Noblett discloses the method wherein the array of reaction sites defines a corner within which the first molecule is located (Column 7, line 21-Column 8, line 4 and Fig. 2 & 7).

Regarding Claim 6, Noblett discloses the method further comprising detecting a second molecule (i.e. fiducial) on the solid support located at a known position and aligning the inspection windows by reference to both first and second molecules (Column 7, lines 61-66).

Regarding Claim 7, Noblett discloses the method wherein imagining is carried out by detecting emitted radiation (Column 7, lines 31-43 and Claim 13).

Regarding Claim 8, Noblett discloses the method wherein the radiation is fluorescent (Column 4, lines 35-49 and Claim 13).

Regarding Claim 9, Noblett discloses the method wherein the molecules of the array are capable of reacting with an analyte i.e. genetic material (Column 3, lines 50-53 and Claims 3-4).

Regarding Claim 10, Noblett discloses the method wherein the molecules of the array are polynucleotides i.e. genetic probe material (Column 3, lines 50-53 and Claims 3-4).

Response to Arguments

6. Applicant argues Noblett does not disclose the instantly claimed method because the fiducial marks of Noblett are not within the actual array of reaction sites but instead positioned at separate and distinct locations away from the array. The argument has been considered but is not found persuasive because Claim 1 is drawn to imaging the array and detecting a signal representing a first molecule located on the solid support at a known position on the array. The claims are not limited to a first molecule within an array of reaction sites as argued. Noblett specifically teaches the method for scanning a microarray comprising detecting a signal

Art Unit: 1634

representing a first molecule (i.e. fiducial mark) at known positions on the microarray (Column 3, lines 24-35). While Noblett teaches that the microarray also comprises sample spots (Fig. 2, 6 & 7) this does not negate the fact that the fiducial marks are at known positions on the microarray as instantly claimed. Furthermore, Noblett teaches that proximity of the fiducial marks to the sample spots facilitates alignment of the sample spots (Column 3, lines 24-35). As such, the fiducial marks of Noblett are on the array and at known positions as instantly claimed.

Applicant argues that in contrast to Noblett, the instant invention is drawn to a method of detecting signals and not a manufacturing process. The argument has been considered but is not found persuasive because as cited above, Noblett discloses the claimed method steps including detecting the presence of the molecules on the array (Column 7, lines 21-67 and Claims 13-16). While Noblett does teach array manufacturing, Noblett also teaches signal detection as claimed and as discussed in the above rejection.

Applicant argues that unlike the Noblett, the instantly claimed method does not require prior knowledge of the relative position between the reference molecule and the other molecules on the array and therefore the claimed method is independent of the manufacturing process. The argument has been considered but is not found persuasive because the argument does not address limitations of the claims and because Noblett teaches the method as claimed. The fact that Noblett also teaches array manufacturing does not negate the fact that Noblett teaching the claimed method of detection.

Applicant further argues that unlike Noblett, the instantly claimed reference molecule is located at a known position on the array. The argument has been considered but is not found persuasive because contrary to Applicant's assertion, the reference molecule of Noblett is at a known position on the array. As stated above, Noblett teaches the method for scanning a microarray comprising fiducial marks at known positions at known positions on the microarray (Column 3, lines 24-35). While Noblett teaches that the microarray also comprises sample spots (Fig. 2, 6 & 7) this does not negate the fact that the fiducial are at known positions on the microarray as instantly claimed. Furthermore, Noblett teaches that proximity of the fiducials to the sample spots facilitates alignment of the sample spots (Column 3, lines 24-35). Therefore, Noblett discloses the method as claimed.

Art Unit: 1634

7. Claims 1, 3-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Juncosa et al (U.S. Patent No. 6,309,601 B1, filed 1 May 1997).

Regarding Claim 1, Juncosa et al disclose a method of imaging molecules contained in an array of discrete reaction sites on the surface of a solid support to detect the presence of molecules on the array, said molecules being detectably labeled (Column 5, lines 43-51) comprising: imaging the array and detecting a first molecule located on the solid support at a known position by reference to the first molecule aligning inspection windows in registration with the discrete reaction sites and determining the amount of detectable signal in each window (Column 4, line 48-Column 5, line 2 and Column 10, line 41-Column 11, line 10) wherein detection of the first molecule is carried out by aligning a first inspection window within a region of the support that includes the first molecule and searching within the window for an image of the first molecule (Column 4, line 48-Column 5, line 2 and Column 10, line 41-Column 11, line 10).

Regarding Claim 3, Juncosa et al disclose the method wherein the first inspection window defines a two-dimensional array of pixels and searching is carried out by scanning diagonally the array of pixels and determining values for the pixels (Column 4, line 48-Column 5, line 2 and Column 10, line 41-Column 11, line 10 and Fig. 6A).

Regarding Claim 4, Juncosa et al disclose the method wherein after detecting the first molecule, the first inspection window is repositioned so that one or more reaction sites is located within the window, detecting the one or more sites and by reference to the first molecule, aligning a further inspection window (Column 10, lines 41-60 and Column 12, lines 1-11).

Regarding Claim 5, Juncosa et al disclose the method wherein the array of reaction sites defines a corner within which the first molecule is located (Column 5, lines 38-51 and Fig 1).

Art Unit: 1634

Regarding Claim 6, Juncosa et al disclose the method further comprising detecting a second molecule (i.e. markers and/or fiducials) on the solid support located at a known position and aligning the inspection windows by reference to both first and second molecules (Column 11, lines 3-10).

Regarding Claim 7, Juncosa et al disclose the method wherein imagining is carried out by detecting emitted radiation (Column 5, lines 43-48).

Regarding Claim 8, Juncosa et al disclose the method wherein the radiation is fluorescent (Column 5, lines 43-48).

Regarding Claim 9, Juncosa et al disclose the method wherein the molecules of the array are capable of reacting with an analyte (Column 5, lines 43-48).

Regarding Claim 10, Juncosa et al disclose the method wherein the molecules of the array are polynucleotides, proteins, antibodies or organic compounds (Column 5, lines 43-48).

Regarding Claim 11, Juncosa et al disclose the method wherein the solid support is less than 1 cm² (Column 6, lines 21-23).

Response to Arguments

7. Applicant argues that while Juncosa teaches a scanning detection system, Juncosa fails to teach or suggest an image processing technique with a grid overlay positioned relative to a known reference molecule. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., grid overlay positioned relative to a known reference molecules) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The method of Claim 1 is drawn a method of imaging an array comprising imaging the array, detecting a signal representing a first molecule, aligning an inspection window in registration with the reaction sites and determining the amount of signal in each window. Juncosa teaches the claimed method as cited above (Column 4, line 48-Column 5, line 2 and Column 10, line 41-Column 11, line 10). The claim does not require or define the use of a grid overlay. As such, Applicant's arguments are not relevant to the claimed method.

Art Unit: 1634

Applicant further argues that Juncosa relies on a complete scan of the whole surface and does not utilize any reference molecule to align further inspection window. The argument has been considered but is not found persuasive because the claims are drawn to a method for imaging an array comprising "imaging the array". The recitation "imaging the array" encompasses the scanning of Juncosa and the open claim language "comprising" encompasses any additional steps of Juncosa. Furthermore, the fact that Juncosa scans the whole surface of the array does not negate the fact that Juncosa does utilize a reference molecule to align further inspection windows as cited above (Column 10, line 41-Column 11, line 10, especially Column 11, lines 3-6). As such, Juncosa discloses the method as claimed.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Juncosa et al (U.S. Patent No. 6,309,601 B1, filed 1 May 1997) in view of Trulson et al (U.S. Patent No. 5,578,832, issued 26 November 1996).

Regarding Claim 12, Juncosa et al teach the method of imaging molecules contained in an array of discrete reaction sites on the surface of a solid support comprising: imaging the array and detecting a first molecule located on the solid support at a known position by reference to the first molecule aligning inspection windows in registration with the discrete reaction sites and determining the amount of detectable signal in each window (Column 4, line 48-Column 5, line 2 and Column 10, line 41-Column 11, line 10) wherein the array comprises

Art Unit: 1634

a solid support (Column 5, lines 38-41) but they are silent regarding the composition of the solid support. However, arrays on solid support comprising ceramic, glass or silicon were well known in the art at the time the claimed invention was made as taught by Trulson et al. Specifically, Trulson et al teach a similar method of imaging molecules contained in an array of discrete reaction sites on the surface of a solid support comprising: imaging the array and detecting a first molecule located on the solid support at a known position by reference to the and determining the amount of detectable signal in each window (Claims 14-22) wherein the solid support is glass, silicon or ceramic material (Column 4, lines 46-67 and Claim 22). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the routinely practiced glass, silicon or ceramic support of Trulson et al to the support of Juncosa et al based on the facts that they are routinely practiced in the art and are the preferred supports Trulson et al (Column 4, lines 66-67).

Regarding Claim 13, Juncosa et al teach the method wherein the molecules are on the surface of the array (Column 5, lines 38-50) but they are silent regarding covalent attachment to the surface. However, covalent attachment was well known and routinely practiced in the art at the time the claimed invention was made as taught by Trulson et al (Column 4, lines 18-20). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the covalently attached molecules of Trulson et al to the molecules of Juncosa et al and to covalently attach the molecules to thereby provide molecules which would remain stably attached under a wide range of experimental and environmental conditions thereby providing a multi-functional and/ or reusable array of molecules. The skilled practitioner in the art would have desired a multi-functional and/or reusable array for the obvious benefits of economy of manufacture and reagents.

Regarding Claim 14, Juncosa et al teach the method wherein the image generated is measured (Column 11, lines 11-48) but they do not teach the image must be above a pre-defined value. However, Trulson et al teach the similar method wherein the image generated

Art Unit: 1634

must be above a pre-determined value i.e. peak (Claim 16). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the image generation of Juncosa et al by determining a predetermined peak value of the image as taught by Trulson et al (Claim 16) thereby obtaining the image at its known peak value for the obvious benefits of optimizing signal detection to thereby maximize experimental results.

Response to Arguments

10. Applicant argues that Juncosa does not teach or describe the method of Claim 1. Trulson does not overcome the deficiencies of Juncosa and therefore Juncosa and Trulson alone or in combination do not render the invention of Claims 12-14 obvious. The argument has been considered but is not found persuasive for the reasons stated above in ¶ 7 regarding Trulson.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1634


Conclusion

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (703) 306-5878. The examiner can normally be reached on 6:30 TO 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


BJ Forman, Ph.D.
Patent Examiner
Art Unit: 1634
March 25, 2003